

INFANT PHOTO-THERAPY UNIT BL-50 B

Manual Book

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1. Summary

Jaundice is a common phenomenon in neonatal period, it is observed that over 90% newborn babies have jaundice in different degree. It can be a physiological phenomenon (called physiological jaundice) in neonatal period, or it can be an important symptom of many diseases in neonatal period (called pathological jaundice). This pathological jaundice can cause bilirubin brain illness (called kernicterus), it can cause brain damage of newborn baby, and results in early death and serious sequela, so we must take immediate and efficient measures to treat neonatal pathological jaundice.

The effect of phototherapy treatment for neonatal high bilirubin blood illness has been approved by clinic, its principle is that bilirubin can absorb rays to have actinic isomerization, it makes the indirect bilirubin oxidize into one water-soluble product under the bluish green light (light-oxidation bilirubin). It fades yellow according to liver and gallbladder discharging out of body. The medical field recognizes that using phototherapy to treat neonatal pathological jaundice is a simple and effective method. Neonatal phototherapy unit are also called “infant phototherapy device” or “blue light lamp”. It is necessary medical equipment of neonatal medical department.

2. Symbols

 Power On  Power Off	 Attention. Consult accompanying documents	INPUT RATINGS : ~110V – 240V 50/60 Hz 20W
 T1AL 250V Fuse Type : T 1AL 250V	 Eye Protection for the PATIENT	Rated power : AC 110V to 240V, 50 or 60 Hz Power input : 20W

3. Use

This product is used for light treatment of high bilirubin for newborn baby.

4. Features:

- 4.1. With its small bulk and light weight, the product has a high efficiency of radiation.
- 4.2. With electron adaptor, power have high adaptive capacity.
- 4.3. LCD display the total time of therapy.
- 4.4. With low, middle, high three level to adjust phototherapy radiant.
- 4.5. Auto save 20.000 hours accumulated use time.

5. Technical parameter

Power supply		AC 110V – 240V 50/60 Hz		
Input Power		±20W		
Effective wavelength		Effective wavelength for distance 36 cm 419 nm, Effective wavelength for distance 50 cm 456 nm,		
Height setting from floor		1007 mm ~ 1745 mm		
Lighting angle setting		360°		
Radiant Head Sizes		382 mm(L) x 230 mm(W)		
LED lamp lifetime		Max 20.000 hours		
LED lamp quantity		17		
Time accuracy		± 1min per 12 hours		
Accumulate time range		0 ~ 20.000 hours		
Count down time range		30 minute ~ 48 hours		
Dimension		503 mm(L) x 430 mm(W) x 1745 mm(H)		
Weight		9,95 Kg		
Working with incubator Distance between the phototherapy equipment and the effective surface area : 36 cm Effective surface area : 50*30cm	Level	High	Middle	Low
	Ebi max (maximum total irradiance for bilirubin)	2800 $\mu\text{W}/\text{cm}^2$	2000 $\mu\text{W}/\text{cm}^2$	800 $\mu\text{W}/\text{cm}^2$
	Ebi avg (The average total irradiance for bilirubin)	2000 $\mu\text{W}/\text{cm}^2$	1400 $\mu\text{W}/\text{cm}^2$	620 $\mu\text{W}/\text{cm}^2$
Working with incubator Distance between the phototherapy equipment and the effective surface area : 50 cm Effective surface area : 60*30cm	Level	High	Middle	Low
	Ebi max (maximum total irradiance for bilirubin)	1620 $\mu\text{W}/\text{cm}^2$	1200 $\mu\text{W}/\text{cm}^2$	480 $\mu\text{W}/\text{cm}^2$
	Ebi avg (The average total irradiance for bilirubin)	1415 $\mu\text{W}/\text{cm}^2$	1000 $\mu\text{W}/\text{cm}^2$	400 $\mu\text{W}/\text{cm}^2$
Working condition of circumtance	Temperature	18°C ~ 30°C		
	Humidity	10% ~ 85% RH		
	Atmospheric pressure	700 hPa ~ 1060 hPa		
Transport and storage condition	Temperature	-10°C ~ +50°C		
	Humidity	≤ 95%		
	Atmospheric pressure	500 hPa ~ 1060 hPa		

Attention: When the distance between the phototherapy equipment and the effective surface area is 35 cm, and the center of effective surface area is a coincide with baby mattress center, Ebi max (maximum total irradiance or bilirubin) is the value center; Ebi avg is the average value of total irradiance for bilirubin between Ebi max and Ebi min.

6. Installation

1. Inspect all goods carefully and against packing list while unpacking. Make sure all parts are intact and not missing.
 - a. Whole unit assembly. (Figure 1)

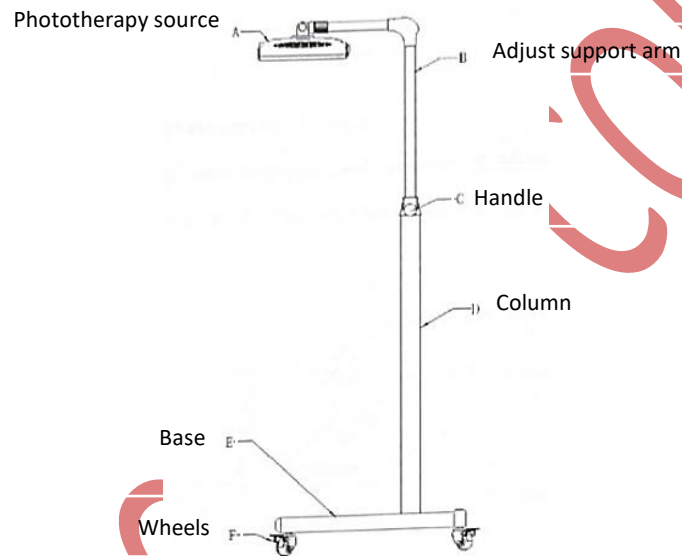


Figure 1

2. Whole unit installation
 - A. Install the column and base

Install four wheels to the base and fixed it.

Use internal hexagon spanner and assist install sleeve, connect the column and base with M8x30 internal hexagon bolt (including flat gasket and spring washer) and fixed it, then cover the four hole with cover cap (Figure 2).

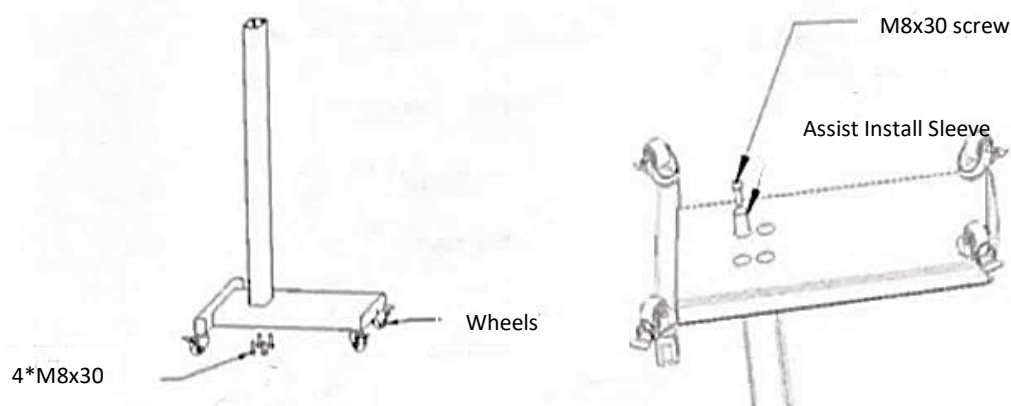


Figure 2

B. Install adjust support arm and phototherapy source

Take out phototherapy source for package, and connect it with adjust support arm with four M4x12 screw. Please attention put the display part in the front. (Figure 3)

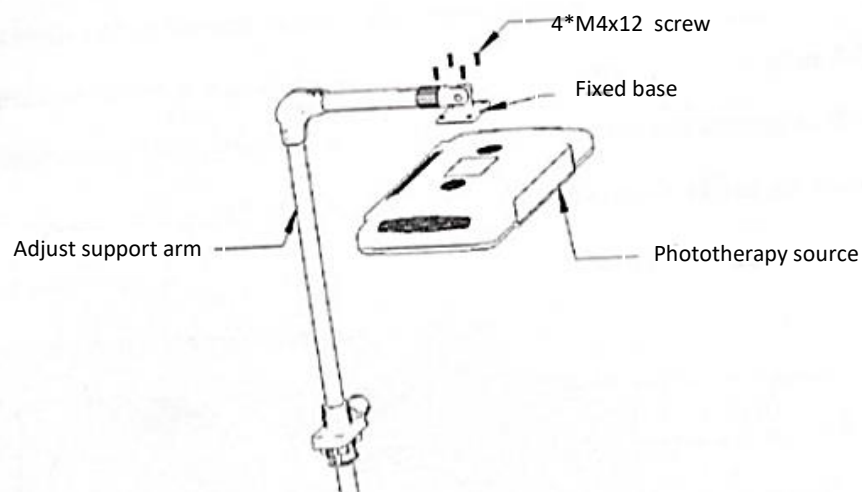


Figure 3

C. Install the whole set

Unscrew handle, move rotate slide to suitable place, hold the phototherapy source with hand, infixed rotate slide to column as fig.4, fixed it use four M8*30 internal hexagon bolt (not including flat gasket and spring washer), attention the direction of rotate slide can't turn over.(Figure 4).

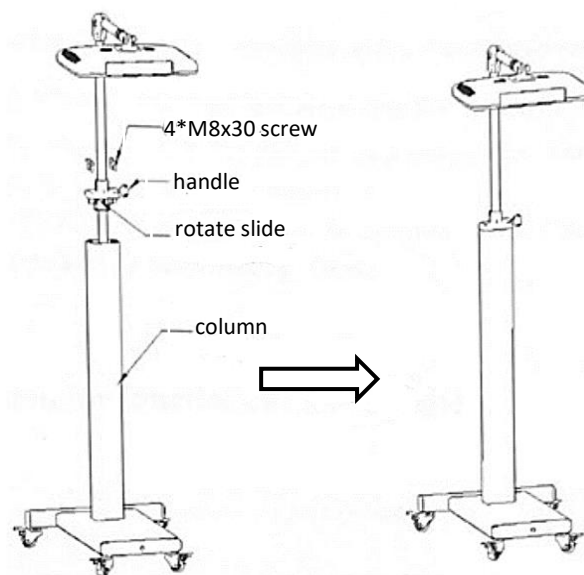


Figure 4

7. Instruction for use

1. Before treating one patient, phototherapy unit should rinse thoroughly and disinfect, avoiding affect the phototherapy effect, especially the lens surface.
2. Put one side of power cable into bear of unit socket, the other side insert AC 110V-240V 50/60 Hz three pin socket (grounding cable of the socket should connect earth very well)
3. Move unit to suitable position, adjust the height and angle of radiant source, fixed the handle.

Some adjust type and range when using as follows :

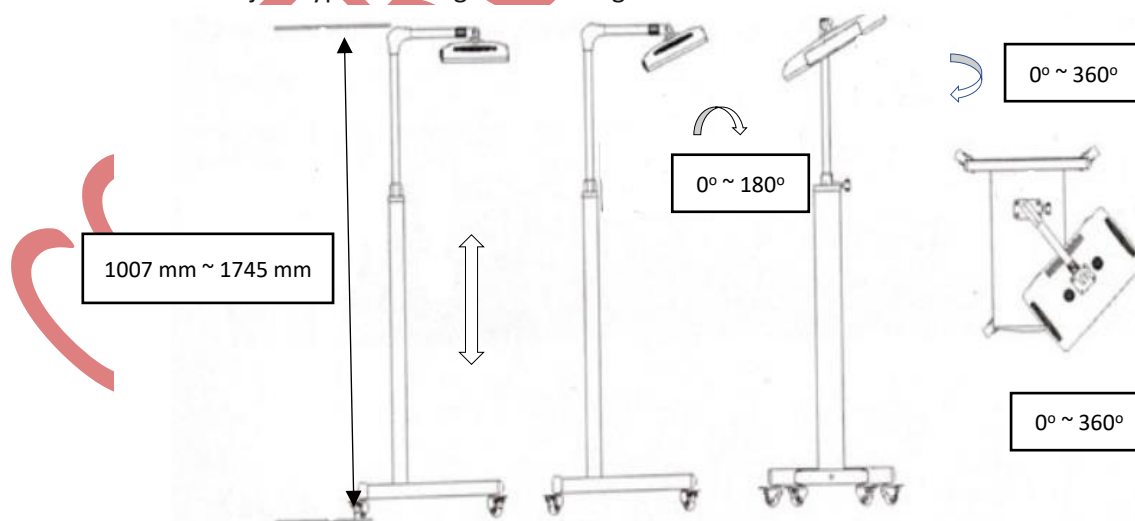


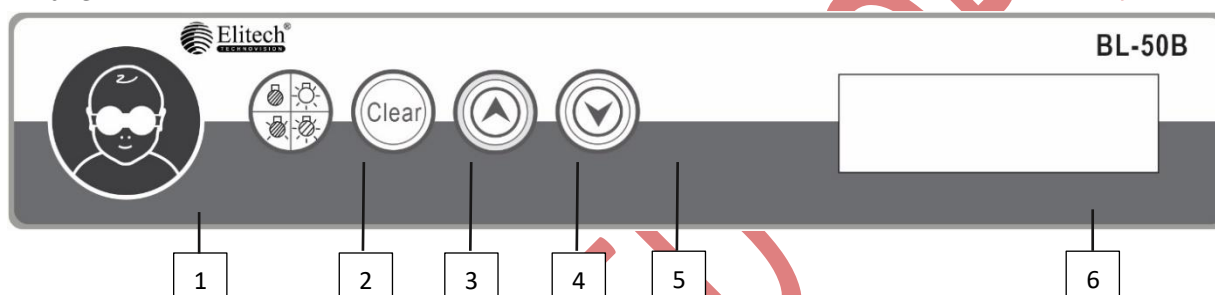
Figure 5

4. When phototherapy, must use light-proof black cloth cover patient eyes or wear blinder, avoid damage the retina when irradiation, blinder elastic should suitable. Switch on phototherapy source and turn on the lamp, timer and treatment is starting.

Attention: Using phototherapy unit will influence the body temperature of the patient, it is very necessary to measure the baby's temperature. Some patients' water balance may be disturbed. So the doctors should supply liquid for the baby for fear of lacking of water

8. Introduction for functions of front panel

1. Panel



- | | |
|------------------|------------|
| 1. Protect Label | 4. Up |
| 2. Light | 5. Down |
| 3. Reset | 6. Display |

2. Function

This unit has high, middle, low three levels, can adjust the irradiance by pressing the light icon key and it will display on the screen, the order is: high – middle – low – pause. ☀ sign means high level, ☁ sign means middle level, ☁ sign means low level, ⏸ sign means pause.

As the fig 6. 🌟🌟🌟 means high level, 🌟🌟 means middle level, 🌟 means low level. All irradiance signs not lightening means phototherapy now is paused.

Attention: when switch off phototherapy unit or cut off, the unit can remember the level of irradiance.

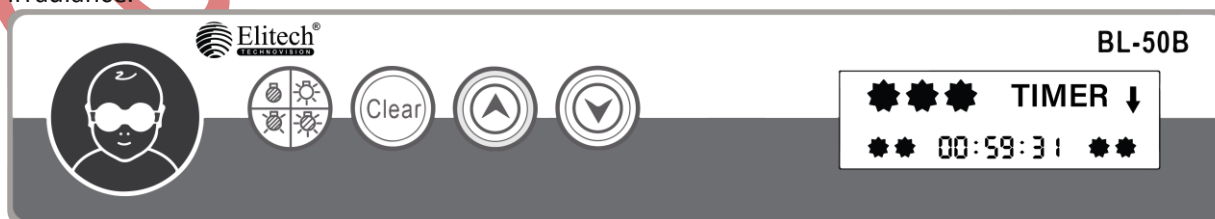




Figure 6

3. Use the timer

3.1. When unit is in paused state, timer stop and display as “hour: minute: second” press  key , turn on lamp, timer continue working.

3.2. Phototherapy unit have the function to auto turn off the lamp at the scheduled time and accumulation timing, if not set this function, default treating is 100 hours, then stop auto. Accumulation time is the total value from initial value to now, and is display as “xxxxx.x”. The max time is 19999.9 hours

3.3. Reset timer : press  and don't move. A few seconds later, timer will reset to zero.

3.4. Set the time for phototherapy (turn off the lamp on time) As fig 7.





- a) Press  key some seconds, enter count down mode, default value is 1 hour. Then can press  or  to increase or reduce count down time, the range is : 30 minutes *n (n = 1-96), when n = 97 and display 0, then the range of irradiate time is 00:30:00-48:00:00'
- b) If set the irradiate time when the lamp is lighten, then the irradiance level not change; if set the irradiate time when the lamp paused, then the irradiance level is high level. And the timer is starting count down till display 0 , then irradiate stopped (display 03:30:00 means it still have three hours and half till end of irradiate.)



Figure 7

- c) Check the time : press  some seconds, timer display cumulative time, then auto change former value (attention, the unit is hour, display with decimalism)

4. If want to end the phototherapy, switch off phototherapy unit and cut off power.

5. Attention

a) Normally is increasing timer for display phototherapy time, the max value is 100 hours; count down timer is decreasing timer for display left phototherapy time, the max is 48 hours.

b) If turn off the phototherapy, the timer display 0, but it will be remembered as accumulative time unless use **CLEAR** key

6. Back panel (Figure 8)

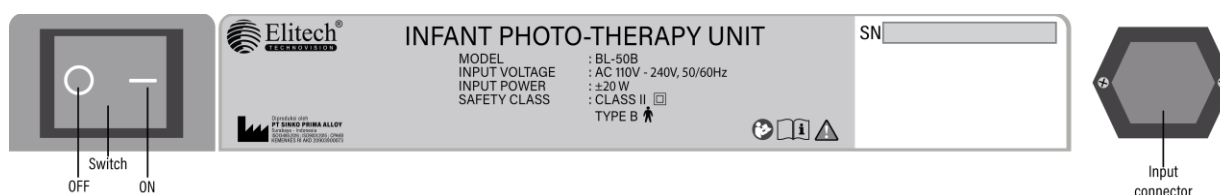


Figure 8

9. Matters need attention

- 9.1. The infant phototherapy unit should be used only by appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known risks and benefits of infant phototherapy unit use.
- 9.2. Castors should be locked when using in order to avoid moving : lock the handle tightly after adjusting correct radiant distance and angle, to avoid unit stand and lamp module moving.
- 9.3. Infant skin should be bare in treatment, hat and socks will also effects the treatment result
- 9.4. When the radiation distance is short, blue ray irradiation watt density is larger, this will add temperature at radiant area. The operator shall choose suitable distance and pay specifical attention of infant skin temperature of radiant area, adjust radiation distance or irradiate treatment discontinuously for infant's safety when necessary,
- 9.5. Use this phototherapy unit maybe effect patient's body temperature, operator must measure patient's body temperature regularly
- 9.6. Patient's water balance, may be disturbed during phototherapy treatment, complement liquid for the infant per your institution's procedures is recommended
- 9.7. During phototherapy treatment, patient's bilirubin values shall be measured regularly per your institution's procedures.
- 9.8. The life time of blue light lamp is 20.000 hours, when the total working time reaching the life time, shall change all the blue light lamps to make sure healing efficacy.
- 9.9. The calibration curve of blue light irradiation meter that test total irradiance for bilirubin as below figure 9-1, abscissa indicates irradiance wavelength, and ordinate shows spectral sensitivity of blue light irradiation meter.

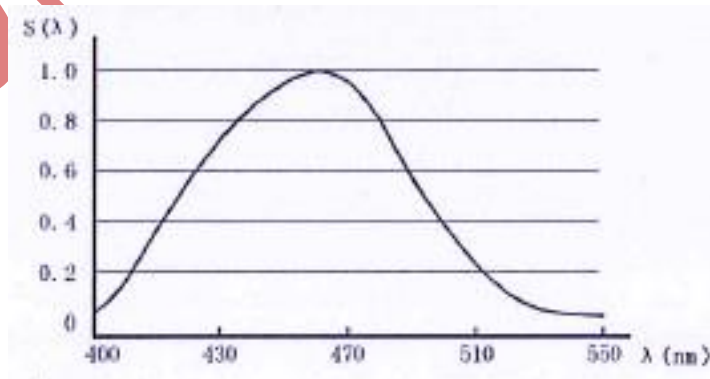


Figure 9-1

- 9.10. The distance of phototherapy source and effect surface more bigger, the average total irradiance for bilirubin more smaller; the distance more smaller, the average value more bigger.

The diagram of wavelength coverage from 400 nm to 550 nm, interval 5 nm total irradiance Ebi curve as follows :

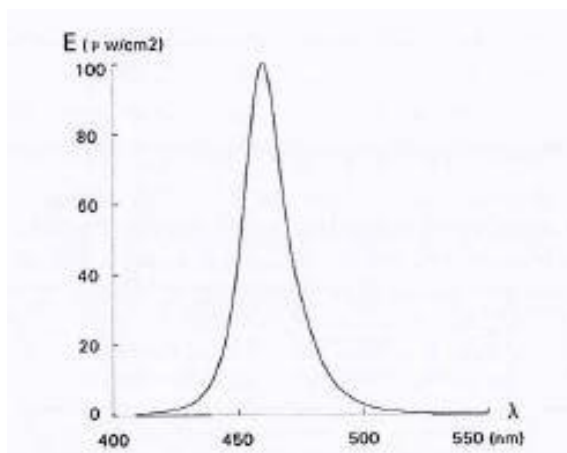


Figure 9-2

- 9.11. The bilirubin photoisomers may cause toxic effects.
- 9.12. Use drape that made of lightproof black cloth and protective glasses to protect patient who come close to the phototherapy unit.
- 9.13. The changing of environment condition such as ambient temperature, different radiation source such as sunlight may influence the safety can healing efficiency. An infant incubator is recommended to work with phototherapy unit together for treatment.
- 9.14. The phototherapy treatment should combine with pharmacotherapy even work exchange transfusion to prevent the bad influence for sick baby that use phototherapy only
- 9.15. Blue light can hinder clinical observations by masking skin color changes, such as cyanosis
- 9.16. Use the protection device to prevent patients to break away from the effective surface area such as infant bed baffle, front door of infant incubator, and regular checks for safety function is necessary.
- 9.17. A. The radiation heat of phototherapy device is increased when work together with infant incubator. Under skin temperature control mode, the skin temperature controller of incubator will reduce heating power of heating element automatically in

accordance with increase of skin temperature which will not affect to baby temperature. Under air temperature control mode, heating power will cause the increase to baby body temperature

B. When photo therapy unit work together with infant radiant warmer that's under auto-mode, the temperature controller of infant warmer could also automatically reduce heating power of heating element to keep stable baby body temperature. When under manual model, the increase of heating power will lead to rise of baby body temperature.

C. When use heating mattress together with phototherapy unit, there is no influence for baby body temperature under skin temperature control mode: But it could also cause the increase of baby body temperature under manual mode.

- 9.18. Use of the baby-controlled mode of the incubator, an infant radiant warmer or heated mattress is recommended, otherwise the set air temperature of the incubator or the heater output of the radiant warmer or heated mattress has to be reduced according to body temperature measurements.
- 9.19. Due to photo effects drugs and infusion liquid shall not be stored in radiation area.
- 9.20. In order to avoid fire, infant phototherapy unit shall not be used in the presence of gases which can support combustion (e.g oxygen , nitrous oxide, anaesthetic agents).
- 9.21. This product service life is 6 years, then should as corresponding law scrap by you or send back to our company.
- 9.22. Don't use phototherapy unit in the environment of portable and mobile radio frequency communication equipment, to avoid the normal work of the device.
- 9.23. The use of reflective foils may cause hazardous body temperatures.
- 9.24. The pre-ageing period is 5 h, stabilization period is 0,5 h.
- 9.25. No goods is allowed to place on the equipment.

10. Warning

! Warning ! During phototherapy, must use opaque black cloth covering with eyes or wear eyeshade to the patient, avoid light on the patients with damage to the retina, patch elastic to appropriate

! Warning ! During phototherapy should use diapers cover genital to prevent damage to the genital function.

! Warning ! The operator may experience some effects during prolonged exposure to the area irradiated by the infant phototherapy unit.

! Warning ! The device is class I equipment. The mode operation of the equipment is continuous operation, it must be grounded reliable.

! Warning ! Use opaque curtain to block the implementation of protection it will affect the care and observation of nurses to patients, proposal increase in the frequency of the care patients, if necessary, should be retained transparent viewing window real-time observation.

! Warning ! When adjusting the lamp box height, handle should not be too loosened to avoid the light pole deviating.

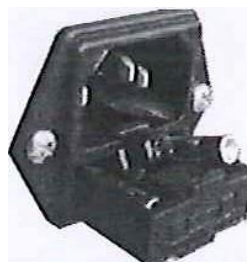
! Warning ! No modification of this equipment is allowed

! Warning ! Prohibited to use this device irradiate bilirubin on the low side of the patients!

! Warning ! Specified LED lamp shall be used. Using parts not be appointed may influence the safety and effectiveness of phototherapy unit.


11. Maintains

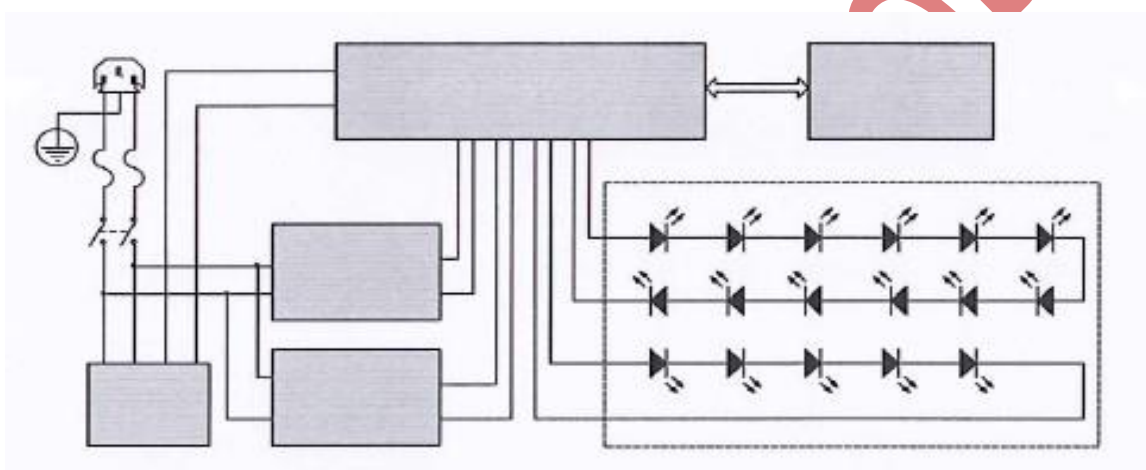
- 11.1. When not using the device, you should pull out the power supply plug.
- 11.2. Use clean cloth to clean the device, especially there should not be dirt on the surface of the light case to keep it clean and bright.
- 11.3. The radiance of the LED lamps will reduce as time passes, you should changes for new LED lamps when using 20.000 hours accumulatively to guarantee the phototherapy effect, its maintain life is 2 months.
- 11.4. Changing fuses: pull out the power supply cord plug and power connecting plug of fuse tube, open the fuse box, and take out the old fuses to change for the same type fuses (TIAL,250V <math><1>5\times 20</math> then push in the fuse box, insert the power supply connecting plug again.



11.5. Common trouble (See table 1)

Table 1

Problem	Cause Analyze	Solutions
All the LED lamps are not lightning	1. Connectors of the wire are not insert well 2. The fuse fail 3. The adapter is broken 4. The equipment with paused state	1. Insert the connectors well 2. Change the fuse 3. Change the adapter 4. Press  key
Some LED lamps are not lightning	1. LED lamps are broken 2. Element protection	1. Change the LED lamp 2. Inspect the circuit
LCD screen not lightning	1. Line panel get loose 2. Circuit board breakdown	1. Weld the lines well 2. Change for a new board



12. After-sale Service

Dear Users:

Thank you for using the medical equipment products that made by our company; please keep this maintenance properly. Products such as defective in quality or breaking down will go on guarantee or maintenance with this list.

Our medical equipment products have two years warranty and lifetime maintenance (except artificially damaged), if the product can't reach technical parameters or other quality problems, please send the "Maintenance List" to our company's service department to find a regulatory solution.



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